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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of Roland Cox : Group Art Unit: 1616
Serial No. 09/529,690 : Examiner: Neil S. Levy
Filed: April 18, 2000

For METHOD OF CONTROLLING HOUSE DUST MITES AND BEDMITES

DECLARATION

I, Roland Cox of 9, Adelphi Close, Littleover, Derby, DE23 3XJ, United Kingdom declare that :-

1. I am the Roland Cox named as the inventor of the invention described and claimed in the specification of the instant Application and named as a co-inventor of the invention described and claimed in the specification of United States Patent No. 5,746,959 (Cox et al.) cited in these proceedings.
2. I have a B.Sc. (Hons.) degree in Applied Chemistry from Nottingham University and am the Technical Business Development Manager for the Amicor business of Acordis Fibres Limited (at the date of the Application, part of Akzo Nobel UK plc). "Amicor" is the Registered Trade Mark for the acrylic fibres manufactured and sold by Acordis Fibres Limited ("Acordis") that incorporate the fungicides, tolnaftate ("Amicor AF") or triclosan ("Amicor AB") or mixtures of those fibres ("Amicor Plus"). These "Amicor" fibres and their manufacture are the subject of the instant Application. I have been involved in the invention, development and marketing of "Amicor" fibres since the inception of the original programme of research in 1995.
3. Commercial development of "Amicor" fibres for the bedding market, now marketed as "Amicor Pure", was started in the United Kingdom in 2000 and has progressed to the sale and use of such fibres across Europe and the United States of America. A range of products incorporates "Amicor" fibres including bed linen, quilts, pillows, mattress protectors, blankets, mattress fillings, ticking, and pyjamas and night wear. These products are marketed by Acordis and its partners in textile production and textile retail as the "Amicor Pure Sleep System".
4. Product and sales development has been accompanied by successful, independent testing of the "Amicor" fibres themselves for humano-ecological requirements and by the conduct of patient trials of bedding made using

"Amicor" fibres to assess their effect on the reaction of patients to bedmite allergens. The successful results of these trials has generated acceptance of "Amicor" fibres for this end use by many authorities, both public and commercial, and has resulted in an expanding business for "Amicor" fibres. I refer to Exhibit RC 1, marked as such and appended hereto, which is a promotional pack distributed by Acordis Fibres Limited to interested parties. This pack contains :-

- A small, generally-blue, folded leaflet, marked "RC1(a)" and titled "Amicor pure", describing the products and the way in which they operate to give the reported benefits.
- A certificate, marked "RC1(b)", from UK testing house BTTG, confirming compliance of "Amicor AB" and "Amicor AF" fibres with the required standards of Oeko-Tex Standard 100 for adult and baby use.
- A Press Release for the Heimtextil textile fair in Frankfurt, on January 9-12th, 2002, marked "RC1(c)", describing, amongst other things, successful trials of "Amicor Pure" bedding carried out with patients over a period of 15 months by the Red Cross Hospital in Barcelona.
- A Report, marked "RC1(d)", of the trials referred to at the Red Cross Hospital in Barcelona.
- A Certificate, marked "RC 1(e)", from the Red Cross Hospital, Barcelona endorsing, as a result of those trials, "Amicor Pure" fibres in minimising the effects of bedmite allergen DER P1 in bedding over a protracted period.
- A Press Release for the Expofil textile fair in Paris, June 4th 2002, marked "RC1(f)", describing the results of research work carried out on behalf of the British Allergy Foundation showing the benefits of using "Amicor Pure" fibres in reducing mites and consequentially, having a notable effect on the amounts present of the allergen Der P1.
- A Seal of Approval, marked "RC1(g)", by the British Allergy Foundation, for "Amicor Pure" anti-bacterial/anti-fungal material, as a result of the research work referred to.
- A Leaflet and Labelling Order Form, marked "RC1(h)", for "Amicor Pure" which demonstrates the branding support given to bedding

manufacturers and retailers across Europe in relation to the "Amicor Pure" Sleep System.

5. I have read the documents cited by the Examiner in these proceedings, particularly WO 97/24484 (Kluft) (and its translation made for the USPTO) and US 4,442,091 (Lebrun), and am aware of the contentions made by the Examiner based upon these documents.

6. Kluft describes a process of applying a mixture of acaracide, biocide and fungicide to fibres using a binder to hold the same in place. In this way, Kluft aims to produce bedding made from such fibres which retains the activity of the acaracide/biocide /fungicide through repeated washing of the bedding. Kluft does not identify specific binders but rather binder types, in particular perfluorinated acrylic compounds. Such compounds are well-known as textile finishes for imparting a level of water-repellance to fabrics. In my experience, it is desirable to avoid putting such a finish onto the surface of fibres used to make bedding articles because they diminish the soft fibre handle which consumers expect in bedding articles. In addition, on reading Kluft, I am not convinced that the product would be effective in fungicidal activity against the Aspergillus species fungi necessary to impact on mite proliferation. I am fully acquainted with the World markets for anti-mite bedding products and fibres for use in such products owing to the commercial activities of my company Acordis in this field. I have never seen a commercial product of the type which the Kluft process is trying to produce.

7. In order to examine the effectiveness of the Kluft process, I asked my colleague, Jon Taylor, to carry out under my direction, the preparation of a treated fibre sample according to that process. This was not straightforward, because Kluft gives no specific examples. It was decided,therefore, to prepare Kluft's preferred combination of agents i.e. a pyrethrinoid as an acaracide together with the biocide/fungicide cocktail of 4-chloro-3-methyl phenol, orthophenyl phenol and (as the glycol ether) di(ethylene glycol) ethyl ether. Kluft's preference for a natural pyrethrinoid is based upon biodegradability, which is not relevant for the purposes of the tests undertaken, and so the more readily-available and more effective permethrin, was used as the pyrethrinoid. The binder used was a commercial water-repellant finish comprising a perfluorinated acrylic material. The fibres chosen for the treatment were acrylic fibres manufactured and sold

by Acordis under the trade -mark "Courtelle" so as to provide comparability with "Amicor" fibres, which are essentially the same acrylic fibres. The preparation of this treated fibre sample is more particularly described in the internal report by my colleague, Jon Taylor, entitled "Preparation of Fibre Samples by the Kluft Method" appended hereto and marked as Exhibit RC2.

8. Lebrun describes the topical application to bedding of natamycin as a fungicide against the Aspergillus species of fungi which relate to the ability of mites to thrive. According to Lebrun, natamycin is effective against the Aspergillus species of fungi and I have no reason to doubt that. Lebrun's method is to apply natamycin to bedding materials as a powder or as a suspension. When the bedding materials are laundered, the natamycin is washed off and therefore repeat topical applications of natamycin to the bedding are required. I understand that it is contended that incorporation of Lebrun's fungicide, natamycin, in Kluft's binder would provide persistent effectiveness against Aspergillus fungi after repeated laundering of bedding materials treated with the same. In my opinion, natamycin is only suitable for use according to lebrun's method i.e. repeat topical applications between launderings. With that method, the poor light stability of natamycin does not matter so much. However, when one is aiming for a textile product which remains fungicidally effective during its lifetime through repeated laundering, I think that the poor light stability of natamycin would rule it out of consideration for this purpose from the beginning. For this reason, I do not think that the proposal of incorporating natamycin in Kluft's binder system is realistic i.e. it would not be done. With regard to the poor light stability of natamycin, reference is made to the website of Danisco, a company which manufactures natamycin for use in the Food Industry under the "Natamax" trade mark. See www.danisco.com/antimicrobials from which two pages are printed as Exhibit RC3, marked as such and appended hereto.

9. Although I am certain that the use of natamycin in Kluft's method would not be entertained, in view of the contention made, I asked my colleague, Jon Taylor, to prepare another treated fibre sample, again according to Kluft's method but substituting Kluft's agents by natamycin as used in Lebrun's process. A sample of pure natamycin was not readily available and so a product used in the Food

Industry, a 50:50 blend with lactose, was used. The preparation of this treated fibre sample is also described more particularly in Exhibit RC2.

10. The fibre samples prepared as specified in Exhibit RC2, have been sent for fungicidal testing by Nottingham Trent University using the test protocol of Swiss Standard SN 195921, a copy of which is appended hereto and marked as Exhibit RC4. The results of that testing will be reported and commented on by me in a second Declaration to be made and filed as soon as the results are received from Nottingham Trent University.

I further declare that all statements herein made of my own knowledge are true and that all statements herein made on information and belief are believed to be true and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment or both under section 1001 of Title 18 of the United States Code and that such wilful statements may jeopardise the validity of the application or of any patent issuing therefrom.

R. Cox

Roland Cox

12TH JANUARY 2004

Date